Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 9th)

The Registration of New Chemical Substances in China from 2021

MEE Order No.12

Speaker
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09/07/2021

Confederation of Indian Industry

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Outline

- Introduction
- Document requirement
- Exam process
- Post-registration Management

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PART I

Introduction

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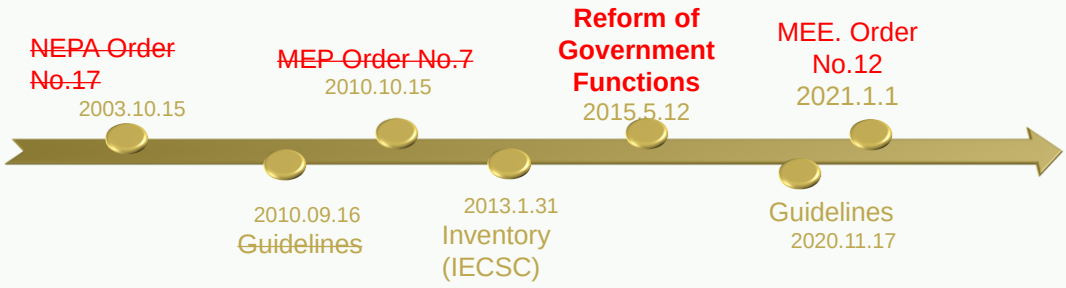
Legislation History



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Registration body

Chinse producers / importers / processing users

Foreign exporters – Agent
Chinese legal personality

Chinese agent:

- registration consulting
  - regulatory compliance assessment
  - data assessment
  - dossier preparation
- test arrangement and supervision
  - OECD GLP lab
  - Chinese lab
  - non-test method
- post registration management
  - IECSC
  - annual report
  - certificate management
- supply chain compliance management

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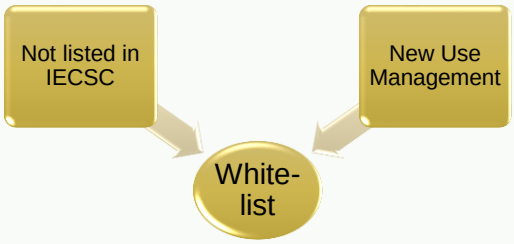
Registration Scope

White-list



Black-list

Exclusion	Exemption
• Chemicals which have already been regulated by other regulations. • Radioactive	• Naturally occurring substances; • Non-commercial or non-intentionally produced substances; • Others;

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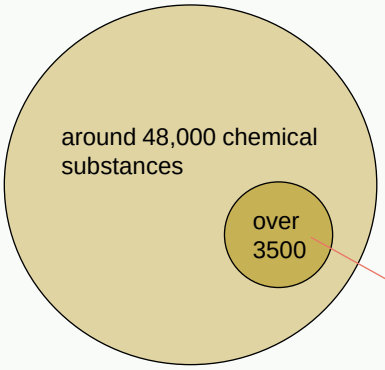
Chemical Inventory: IECSC

IECSC – Inventory of Existing Chemical Substances Produced or Imported in China



Confidential!!!
3000 RMB

《中国现有化学物质名录》2013 年版
IECSC Ver. 2013 Public Part

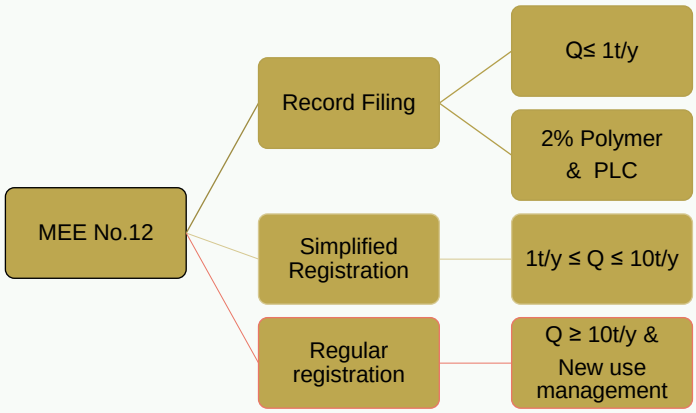
序号 No.	中文名称 Chinese chemical name	中文别名 Alias	英文名称 English chemical name	英文别名 Alias	分子式 Formular	CAS 号 或美术号 CAS or Serial No.
1	叶丙啶的有聚物与氯甲基环氧乙烷的反应产物		Aziridine, homopolymer, reaction products with epichlorohydrin	Polyethylenimine, epichlorohydrin condensate;Polyethylenepolyamine, epichlorohydrin condensate; Polyethylenepolyamine, epichlorohydrin reaction product;Polyethylenimine, epichlorohydrin adduct	$(C_2H_5N)_x·C_3H_5ClO$	68037-89-1
2	[3-(1-叶丙啶基)丁基]氨基甲酸		Carbamic acid, [3-(1-aziridinyl)butyl]-			227358-49-7
3	叶啶	氮丙	Aziridine		C_2H_5N	288-94-8
4	N-[2-[[4-[9-叶啶基氨基]苯基]氨基]-2-氧代乙基]-4-氨基-1-甲基-1,9-吡咯-2-甲酰胺		1H-Pyrrole-2-carboxamide, N-[2-[[4-[9-acridinylamino] phenyl]amino]-2-oxoethyl]-4-amino-1-methyl-			126892-91-9
5	阿卡代特 15		Alkadet 15			82870-30-6
6	D-阿拉伯-2-己糖醛酸	α-酮戊二酸-α-氧代戊二酸-α-酮酸酸	D-Arabino-2-hexulosonic acid	α-Ketoglutaric acid	$C_6H_{10}O_7$	669-90-9
7	阿拉伯酶		Arabinase			37321-54-5
8	阿拉伯树胶	树胶粉	Gum arabic	Gum acacia		9000-01-5
9	阿拉伯树胶聚合物萃取物		Acacia concinna, ext.			2021-89-87-8
10	阿拉伯糖胞苷		Cytosine arabinoside Cytosine	AC-1075; Alexan; 4-Amino-1-arabinofuranosyl-2-oxo-1,2-dihy	$C_9H_{13}N_3O_5$	147-94-4

PART II

Registration Requirement

Registration Types (1)

Normal registration types



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Registration Types (2)

Special registration types

- **Joint registration**
  Applicant 1 +2+3 … +N → same substance
- **Series registration**
  An applicant --> substance 1 + 2 … +6 similar substances
- **Repeat registration**
  Removed!

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Dossier Preparation

Record Filing	1) Application form 2) subject qualification documents 3) CBI documents 4) Other in-hand information	*Polymer record filing proof!*
Simplified Registration	5) Commitment letter 6) Physical & chemical data 7) Eco-toxicological data 8) TI qualification	*PBT determination (conclusion and basis) is required!*
Regular Registration	9) toxicological data 10) Environmental risk assessment report 11) Social-economic assessment report (Highly hazardous chemical substance)	

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PART III

Assessment

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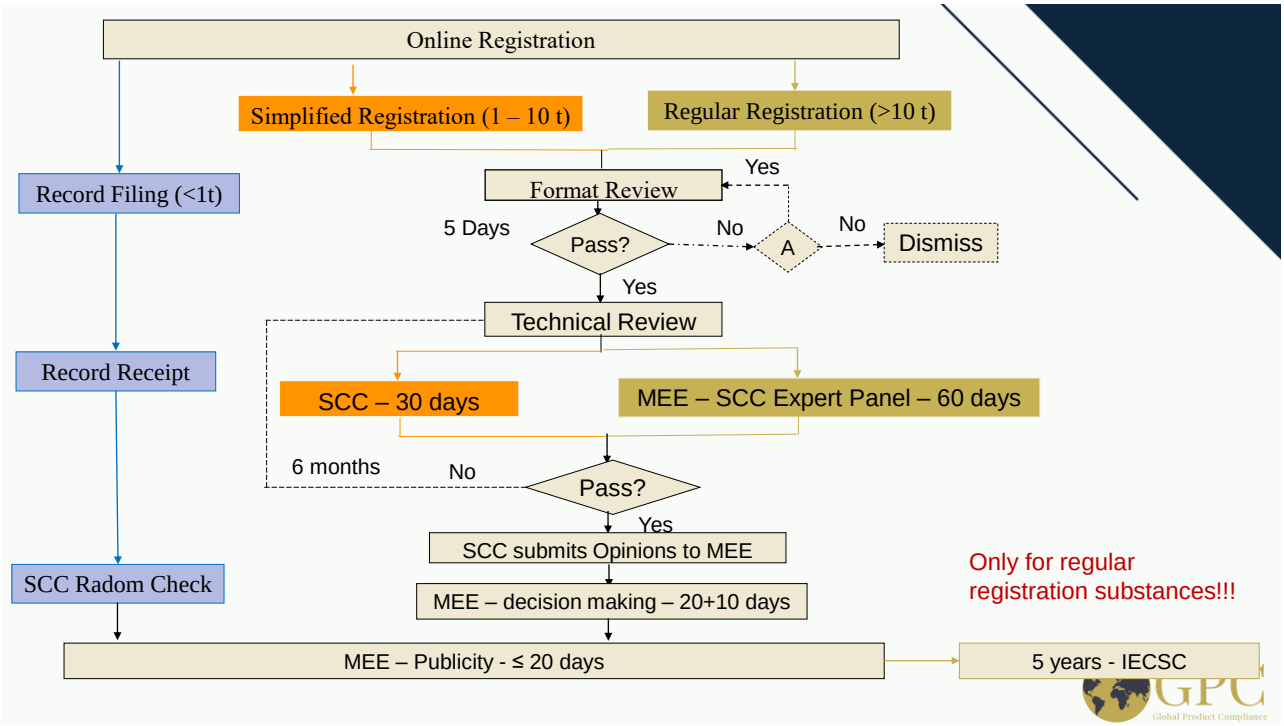

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Approval Criteria

Record Filing

Complete Online Registration

Simplified Registration

No PBT
+
No Cumulative Environmental Risk

Regular Registration

No Unreasonable Risk
+
Highly Hazardous Chemical Substance (necessity)

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Procedures for inclusion of IECSC

All the inclusion is done after a public announcement!

Regular registration

- Under No.17 → 6 months after the application of Order No.12
- Under No.7 → 5 years after the application of Order No.12
- Under No.12 → 5 years since registration

Prior to 15th October 2003 → nomination window → provide evidence

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PART IV

Post-Registration Management

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Post-registration Obligations

Activity report

- First activity report
within 60 days
time / place / volume / risk management / processing user

- Annual report
30th April
activity / emission / risk management

Information disclosure

Regular registration

- producer and processing user
- publish environmental risk control measures and real situation
- official website

Information communication

To downstream users

- registration number
- purpose of use
- risk and its management
- environmental protection requirement as listed on certificate

Post-registration Obligations

New Hazardous Information & Environmental Risk

- report to MEE
- adopt measures to minimize the risk
- online record / information disclosure

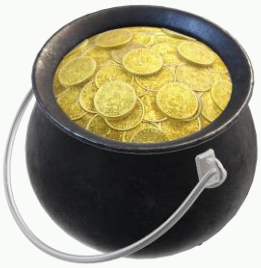
Data Record

10 / 3 years

- record system (digital measure)
- Time / volume / purpose / risk / etc.

Legal Liabilities

Monetary Punishment
Up to 30,000 RMB



Behavioral Punishment
Correction

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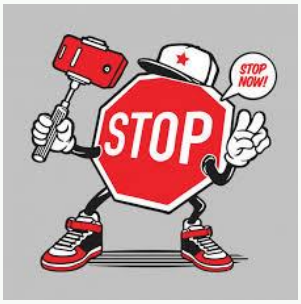
Legal Liabilities

Administrative Punishment

Not Accepting Application / Report up to 3 years



Loss in Social Credits

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Take home message

Do's

- Specify certain clause in agreement with agent
- Joint and series registration
- Do toxicological test in Chinese certified Lab
- Be honest!

Don'ts

- Transfer to importers?
- Repeat registration
- Other labs data / data from other REACH
- No fake or illegal information is allowed

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Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 9th)

Chemical Regulation in Taiwan and recent updates on registration

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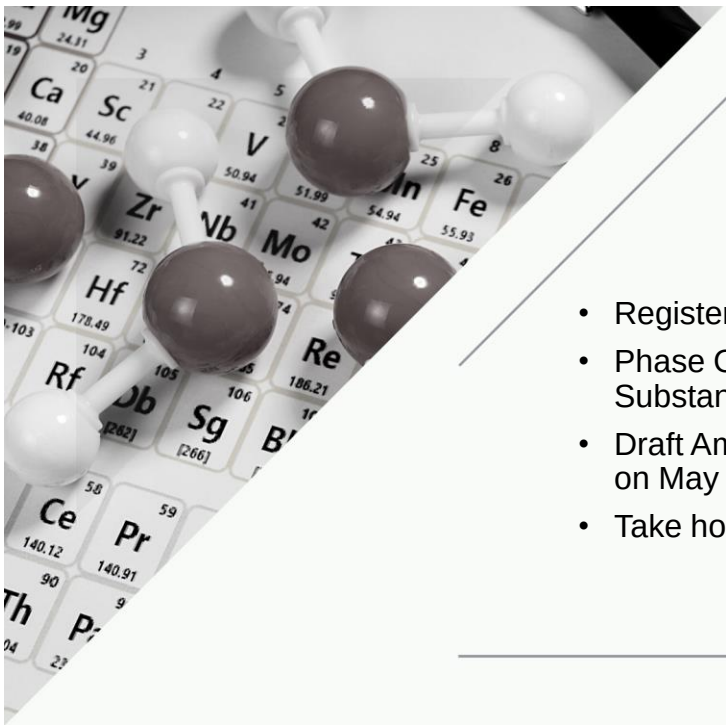

Summary of Topics

- Register Substances in Taiwan
- Phase One Registration and Priority Existing Substances (PECs) Registration
- Draft Amendment to Registration (published on May 27th)
- Take home message

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Chemical Regulations in Taiwan:

Chemicals at Workplace:
The Ministry of Labor

Occupational Safety and Health Act(OSHA);

- Hazard Communication (GHS)
- Priority Management Chemicals
- Controlled Chemicals

Industrial Chemicals:
Environmental Protection Administration (EPA)

Toxic and Concerned Chemical Substance Control Act (TCCSCA)

- Class 1,2,3, and 4 of Toxic Substances
- Concerned Substances

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Toxic and Concerned Chemical Substance Control Act

- Toxic and Concerned Chemical Substance Control Act (TCCSCA),
  - enacted on 16 January 2019
  - amended, and renamed from Toxic Chemical Substance Control Act (TCSCA)
  - enforced since 1st January 2020
- Regulation on New and Existing Chemical Substances (March 2019)
- On May 27, 2021: Taiwan's EPA proposed an amendment to the Regulation on New and Existing Chemical Substances.
  - open for public consultation until July 26.

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After January 16th 2019

Toxic Chemicals Substances Control Act (TCSCA)

- Chapter 1 General Principles
- Chapter 2 Hazard Assessment and Prevention
- Chapter 3 Management
- Chapter 4 Panel Provisions
- Chapter 5 Supplementary Provisions

Toxic and Concerned Chemicals Substances Control Act (TCCSCA)

- **Chapter 1** General Principals (§ 1-7)
- **Chapter 2** Assessment, Prevention and Management of Toxic Chemical Substances (§ 8-23)
- **Chapter 3** Assessment, Prevention and Management of Concerned Chemical Substances (§ 24-29)
- **Chapter 4** Registration and Reporting of Chemical Substances (§ 30-34)
- **Chapter 5** Accident Prevention and Emergency Response (§ 35-43)
- **Chapter 6** Audit, Inspection, and Financial Matters (§ 44-49)
- **Chapter 7** Penal Provisions (§ 50-67)
- **Chapter 8** Supplementary Provisions (§ 68-75)

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Regulation on New and Existing Chemical Substances

- Taiwan Chemical Substances Inventory (TCSI) contains 100,000+ substances that were manufactured in or imported in Taiwan between 1993 and 2014
- For Existing Chemical Substance (those listed in TCSI):

  Phase One Registration

  106 PECs: Standard Registration – level 1- 4
- For New Chemical Substance (those not listed in TCSI):
  Depending on tonnage: simplified, small quantity and standard registration

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Exemption

- Substances which occur in nature.
- Chemical substances in machines or equipment for test run purposes.
- Inseparable intermediates from chemical reactions in the reaction vessel or production process.
- Chemical substances for national security or national defense purposes.
- Chemical substances under customs supervision.
- Chemical wastes produced or released from industrial process.
- By-products or impurities that are of no commercial application.
- Mixtures; but individual constituents of mixtures shall not be applied to the Article.
- Articles
- Polymers that the 2% Rule is Applicable and listed on the inventory of existing chemical substances.

- Agro-pesticides, as defined by the Agro-pesticides Management Act.
- Feeds and feed additives, as defined by the Feed Control Act.
- Fertilizers, as defined by the Fertilizer Management Act.
- Veterinary drugs, as defined by the Veterinary Drugs Control Act
- Medicaments, as defined by the Pharmaceutical Affairs Act.
- Controlled drugs, as defined by the Controlled Drugs Act.
- Cosmetic(s), as defined by the Statute for Control of Cosmetic Hygiene.
- Foods, food additives, food utensils, food containers or packaging, and food cleansers, as defined by the Act Governing Food Safety and Sanitation.
- Tobacco products, as defined by the Tobacco Hazards Prevention Act
- Tobacco and alcohol, as defined by the Tobacco and Alcohol Administration Act.
- Radioactive materials, as defined by the Atomic Energy Act and the Ionizing Radiation Protection Act.
- Industrial use explosive materials, as defined by the Industrial Explosives Administrative Act.
- Chemicals regulated by the Montreal Protocol under the Air Pollution Control Act.
- Environmental agents, as defined by the Environmental Agents Control Act.
- Toxic chemical substances, as defined by the Act.

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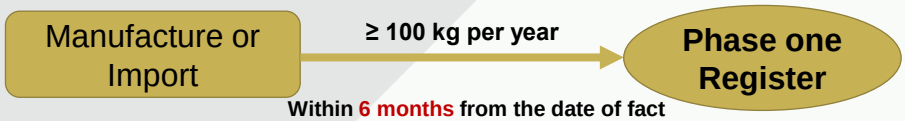
Existing Chemicals: Phase One Registration



Within 6 months from the date of fact

Information required:

1. **Name of substance, CAS No.**
2. **Tonnage band in a calendar year (estimated)**
3. **Information on use**
4. **Use information of this chemical (Product type)**

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Existing Chemicals: Standard Registration

Article 16 of the regulation:

- The central competent authority may, by stages, **designate the lists of existing chemical substances subject to standard registration…**
- The first batch of PECs: 106 PECs (Appendix 6)
- Above 1 TPA : 1- 4 levels
- Information requirement (Appendix 7)
- Registration starts from 1 January 2020

類別 Stage	序號 Serial No.	化學文摘社登記號碼 CAS No.	英文名稱 English Name	中文名稱 Chinese Name
1	1	79-10-7	Acrylic acid	丙烯酸
1	2	10043-01-3	Aluminium sulfate	硫酸鋁
1	3	7664-41-7	Ammonia, anhydrous	氨，無水
1	4	1336-21-6	Ammonium hydroxide	氫氧化銨
1	5	123-77-3	1,1'-Azobis(formamide)	1,1'-偶氮雙(甲醯胺)
1	6	100-52-7	Benzaldehyde	苯甲醛
1	7	552-30-7	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride	苯-1,2,4-三甲酸 1,2-酐
1	8	119-61-9	Benzophenone	二苯基酮
1	9	25973-55-1	2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol	2-(2H- 苯 并 三 唑 -2-基)-4,6- 二 三 級 戊 基 苯 酚
1	10	90-43-7	2-Biphenylol	2-苯基苯酚
1	11	103-23-1	Bis(2-ethylhexyl) adipate	己二酸雙(2-乙基己基)酯
1	12	106-94-5	1-Bromopropane	1-溴丙烷
1	13	111-76-2	2-Butoxyethanol	2-丁氧基乙醇
1	14	25013-16-5	Butylated hydroxyanisole	丁基化羥苯基甲基醚
1	15	128-37-0	Butylated hydroxytoluene	丁基化羥基甲苯
1	16	57693-14-8	C.I. Acid black 172	C.I. 酸性黑 172
1	17	105-60-2	ε-Caprolactam	ε-己內醯胺
1	18	1333-86-4	Carbon black	碳黑
1	19	95-48-7	o-Cresol	鄰甲酚
1	20	108-77-0	Cyanuric chloride	三聚氯化氰
1	21	108-94-1	Cyclohexanone	環己酮
1	22	95-33-0	N-Cyclohexyl-2-benzothiazolesulfenamide	N-環己基-2-苯并噻唑亞磺醯胺
1	23	108-91-8	Cyclohexylamine	環己胺
1	24	1309-64-4	Diantimony trioxide	三氧化二銻
1	25	1303-86-2	Diboron trioxide	三氧化二硼
1	26	80-43-3	Dicumyl peroxide	過氧化雙異苯丙基
1	27	7173-51-5	Didecyldimethylammonium chloride	氯化二癸基二甲基銨

Examples of Priority Existing Chemicals (PECs): Acrylic acid, Ammonia, Diboron trioxide

PECs Standard Registration Dossier

* The highest number of data required for submission

	Section	Level 1 (1-10 tons)	Level 2 (10-100 tons)	Level 3 (100-1000 tons)	Level 4 (1000+ tons)
1	Information of the registrant and basic identification of the substance	v	v	v	v
2	Information on manufacture, use and exposure of the substance	v	v	v	v
3	Hazards classification and labelling	v	v	v	v
4	Safe use information	v	v	v	v
5	Physical and chemical properties	v(13)*	v(13)	v(15)	v(15)
6	Toxicological information	v(5)	v(8)	v(8)	v(9)
7	Ecotoxicological information	v(3)	v(7)	v(9)	v(16)
8	Hazard assessment		v	v	v
9	Exposure assessment		v	v	v

Data sharing applicable to Section :3, 5, 6, 7, (8)
Guidance for Existing Chemical Substances Standard Registration (Version 1) – June 2020

Type of data acceptable for standard registration:
1. **International Public Information**
2. One of following
QSAR Estimation
Read Across
Systematic Review
Testing Proposal
3. Testing report

New Chemical: Registration

information requirement

	Section	Small quantity Registration	Simplified Registration	Standard Registration
1	Information of the registrant and basic identification of the substance	v	v	v (Level 1)
2	Information on manufacture, use and exposure of the substance	v	v	v (Level 1)
3	Hazards classification and labelling		v	v (Level 1)
4	Safe use information		v	v (Level 1)
5	Physical and chemical properties		v	v (Level 1)
6	Toxicological information			v (Level 1)
7	Ecotoxicological information			v (Level 1)
8	Hazard assessment			v (Level 2-4)
9	Exposure assessment			v (Level 2-4)

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New Chemical: Registration

Item	≤100 kg	100 kg - 1 ton	1 ton -10 tons	10 tons -100 tons	100 tons – 1000 tons	1000 + tons
New Chemical Substance	Small quantity Registration	Simplified registration	Standard Registration (Level 1)	Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)
Scientific Research and Development			Simplified registration		Standard Registration (Level 1)	
Process oriented Research and Development (PRORD) On-site isolated intermediates Polymer	Small quantity Registration		Simplified registration		Standard Registration (Level 1)	
Polymer of Low[1] Concern			Small quantity Registration			
CMR Substance	Standard Registration (Level 1)		Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)	

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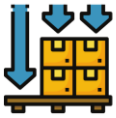
Who can register?

Manufacturer



Importer

Third Party Representative (TPR) with legal entity in Taiwan

How can TPR help you and your company?

- Supply Chain Communication – communicate directly with your Taiwanese buyers to proceed TPR appointment and submit information to Toxic and Chemical Substances Bureau, EPA
- Phase One Registration/Standard Registration (include Dossier Preparation)

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Join Registration

- Joint Registration is not mandatory.
- Communication with the agency: it may take longer time for dossier review from the authority, and back-and forth conversations.
- Prepare your dossier to meet the deadline

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Annual Reporting

The first Annual Reporting for Registered Chemical Substances took place during April 1st to September 30th 2020.

Manufacturers, importers and authorized TPR with valid Registration Number are eligible for Annual Reporting

Information to be included in Annual Reporting:

- Substance name
- CAS Number
- Registration number for each substance
- Volume in the previous year
- Information on importer or manufacturer

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Background to the Amendment Draft

- To review the registration process and the actual registration situation
  - By June 1, 2021: Cases of Standard Reg. 51 (1-10 TPA), 5 (10-100 TPA), 2 (100+ TPA), 14 polymer (10+TPA),
- To include opinions from stakeholders and industries
- Delayed preparation for registration due to COVID 19
- The draft is announced on May 25 and open for public comments until July 26, 2021

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Key Change (1/5)

- Newly Added Exempted Substances
  - Controlled chemicals defined by Occupational Safety and Health Act, Regulations Governing Designation and Handling Permission of controlled Chemicals
  - Concerned Chemical Substances defined by TCCSCA, risk to environment and human health
- Valid Period of Registration and Confidentiality are extended to 5 years

Type of registration	Valid Period of Confidentiality
New Chemical Substance - Standard Registration PLC Small quantity registration	5 years
New Chemical Substance – simplified registration and small quantity registration	~~2~~ 5 years
Existing chemical substance – Phase One Registration, Standard Registration	5 years

Max. confidential period is ~~10~~ 15 years

Max. confidential period is 15 years

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Key Change (2/5): Review period

	Current Regulation	Draft Amendment	Estimated Application process
Phase One Reg.	7	10	2-4 weeks
Small Quantity Reg. (New Substances)	7	10	2.5 months
Simplified Reg. (New Substances)	14	20	5-6 months
Standard Reg. (New Substances)	45	60	11 to 13 months
Standard Reg. (Existing Sub.)	90	90	1 to 1.5 year
Application for CBI extension	7	10	
Application for inclusion to TSCI	14	20	

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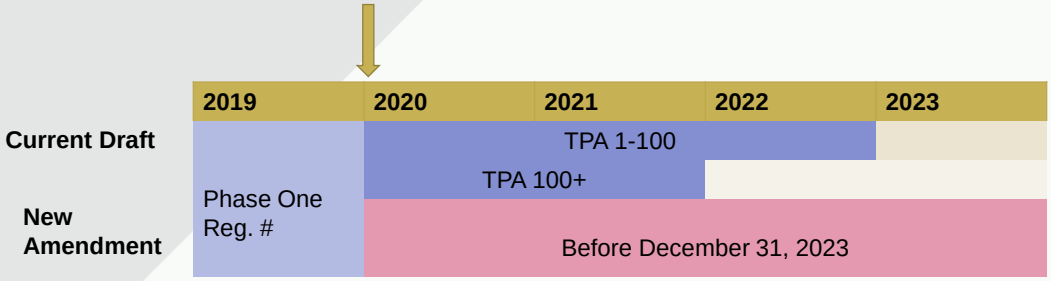
Key Change (3/5)

Phase One Registration Number obtained before December 31, 2019



Deadline for Standard Registration extended to 4 years

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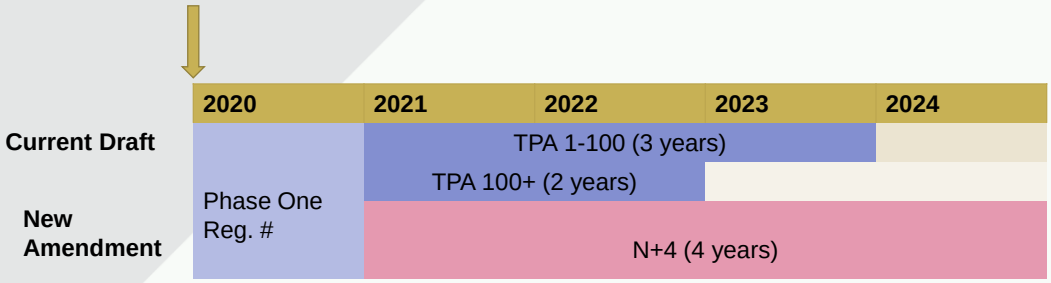
Key Change (4/5)

Phase One Registration Number obtained after January 1, 2020



Deadline for Standard Registration extended to 4 years

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Key Change (5/5): Standard Reg.

	Section
1	Information of the registrant and basic identification of the substance
2	Information on manufacture, use and exposure of the substance
3	Hazards classification and labelling
4	Safe use information
5	Physical and chemical properties
6	Toxicological information
7	Ecotoxicological information
8	Hazard assessment
9	Exposure assessment

Current Draft: Registration No. can be obtained if all required information approved by the authority

Draft Amendment: Registration No. can be obtained if 1-7 information approved by the authority. The rest can be submitted within suggested time.

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Take Home Message (1/2)

- Understand your registration obligation and start to prepare your dossiers as soon as possible.
- Joint registration is not mandatory.
- Expecting inquiries from your downstream buyers for compliance check
- Contact TPR to have professional support from experienced team

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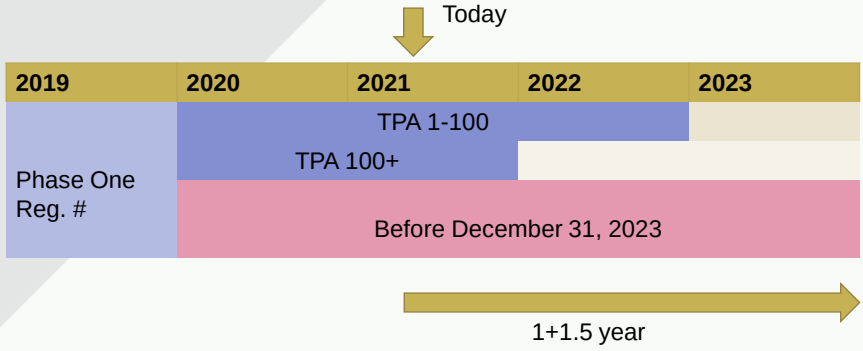
Take Home Message (2/2)

- **Phase One Registration Number** obtained before December 31, 2019
- Expect 1.5 year submission period



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Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 9th)

Poison Centre Notification (PCN) & Its Implications on SDS

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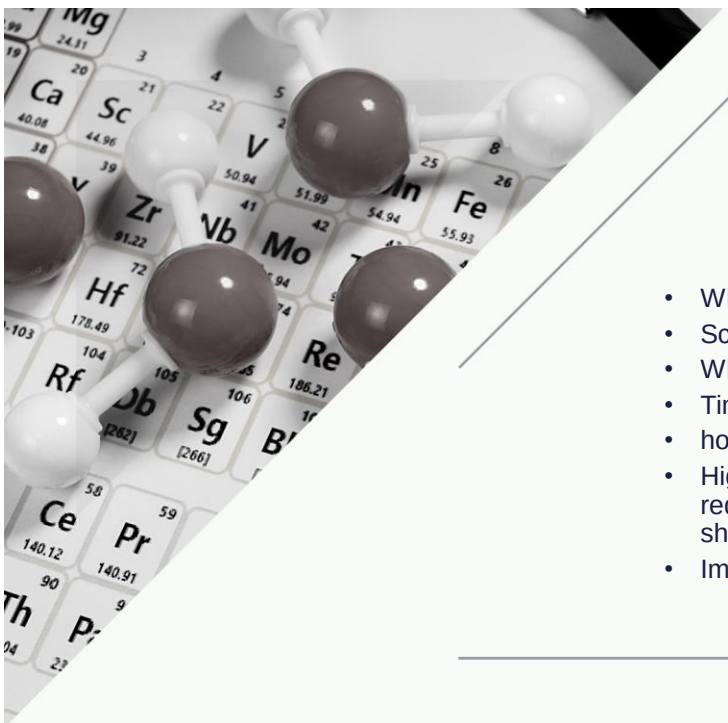

Summary of Topics

- What is Poison Centre Notification (PCN)
- Scope of PCN
- What are the obligations within PCN
- Timelines for compliance
- how to start preparing notifications
- Highlight harmonised information requirements beyond the safety data sheet
- Implications on SDS

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What is Poison Centre Notification?

Article 45 of the Classification, labelling & Packaging (CLP) Regulation:

companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies.

Annex VIII to the CLP Regulation (adopted in March 2017)

harmonised requirements for poison centre notifications (PCN) applicable as of 1 January 2021*

European Chemicals Agency (ECHA)

Tools, guidance and support

https://poisoncentres.echa.europa.eu/

CLP Regulation – Annex VIII

- Harmonisation of information requirements for certain hazardous mixtures in all EU Member States
- Preparation of data in a harmonised submission format (.xml)
- For use by poison centres for the purposes of making an emergency health response

What mixtures are in scope?

- Mixtures classified for human health or physical effects
- Does NOT include mixtures:
  - classified only for environmental effects/gases under pressure/or explosives
  - used in scientific research & development
  - not covered by CLP Regulation

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Exemptions in PCN

- Mixtures not covered by CLP Article 2:
  - medicinal products
  - veterinary medicinal products
  - cosmetic products
  - medical devices which are invasive or used in direct physical contact with the human body
  - food or feeding stuffs including when they are used as food additives or flavourings in foodstuffs, additives in feeding stuffs or in animal nutrition.
- Mixtures used for Research and & Development
- Mixtures classified only for environmental effects
- Mixtures classified only for gases under pressure and/or explosives (unstable explosives and Division 1.1 to 1.6).

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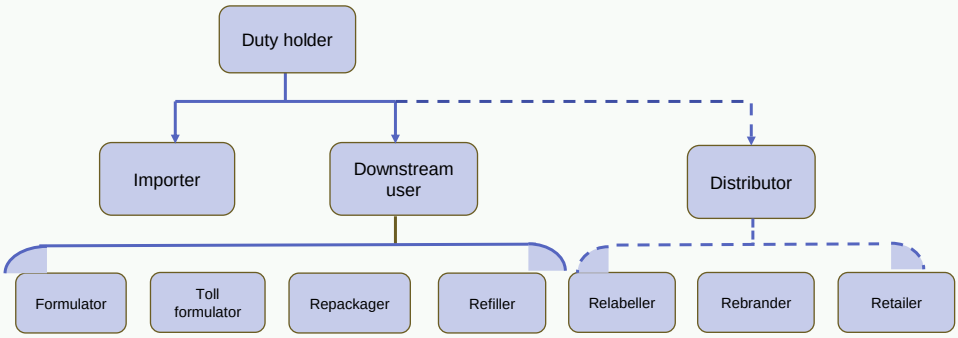
Obligations under Article 45 & 4(10) CLP

- Stipulates general obligations to comply also for distributors
- *'Substances and mixtures shall not be placed on the market unless they comply with this Regulation'.*



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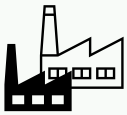
Who <u>can</u> submit information?

For example, EU based:

Legal entities on behalf of duty holders, such as consultant, mother company, i.e. 'Foreign user'



Importers or downstream users of mixtures out of scope i.e. a voluntary submission

Legal representative of non-EU suppliers can also make a submissions through the EU legal entity

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Timelines for compliance

- Notifications must comply with the harmonised requirements according to the use type of the mixture
- Transition period for existing products ends 1 January 2025
- unless change made to existing notification between relevant deadline and end of transition period

*This deadline has been recently extended

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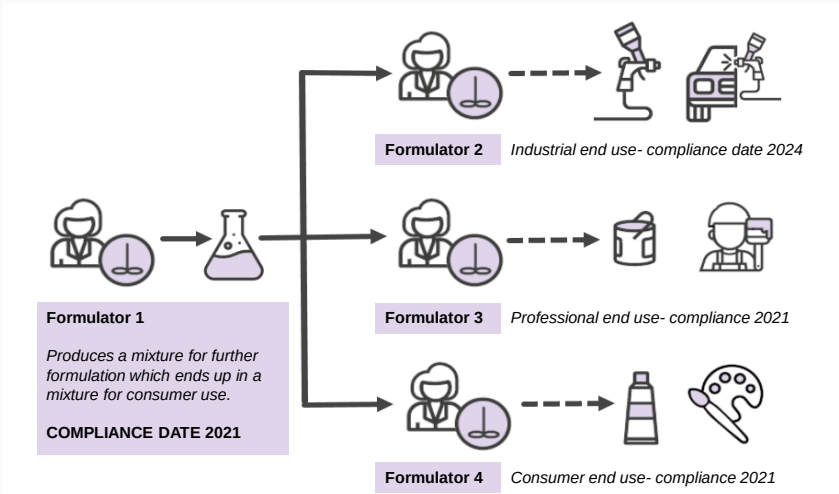
Compliance date depends on end use



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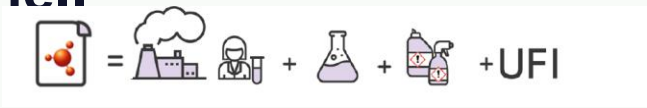
Harmonised requirements in a nutshell



- Submission format –Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- Submitter details –name, address etc. -consistent with the label
- Product information -trade name, packaging, uses, colour
- Mixture information -C&L, toxinfo, composition, pH, physical state
- Unique formula identifier –e.g. YV9K-3J9A-G209-C2T7,
- Unique formula identifier(UFI) makes a link between the product and the submitted mixture information

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Mixture information

- All the complete trade name or names of the mixture/product as they appear on the label.
- Toxicological information as required in Section 11 of the Safety Data Sheet* in all languages required by the prospective Member States.
- Hazard classification and labelling information
  - Hazard class and category, hazard pictogram codes, signal word, hazard and precautionary statement codes
- Physico-chemical properties i.e. colour, pH and physical state.

* The SDS is not an information requirement and cannot replacement the toxicological information required.

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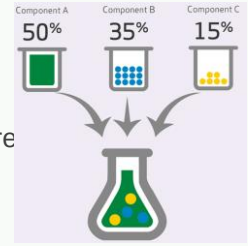
Mixture composition

- Details of all mixture component (substances and **MiMs**) concentrations to 100%:
  - Classified components when in concentrations ≥0.1%
  - Not classified components when in concentrations ≥1%
- Product identifiers
  - Substance chemical names, CAS/EC numbers, IUPAC, INCI where applicable (in accordance with Article 18(2) CLP).
  - MiM trade name, UFI where applicable



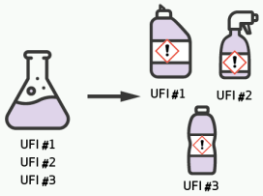
- Hazard classification of components (labelling information not required).

The SDS is not an information requirement and cannot replace the toxicological information required.

UFI and other identifiers of the mixture/product

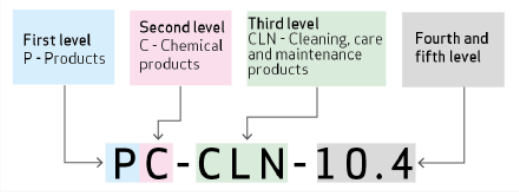
- At least one unique formula identifier (UFI) must be assigned to the mixture being placed on the market.
- Note that one mixture composition may have multiple UFIs assigned to it which may correspond to different products (with the same mixture composition).

Other identifiers may be optionally included by the submitter, for example, previous national notification numbers.



Product information

- Use type of the mixture, or a combination of the three considering the end use:
  - consumer
  - professional
  - industrial
- A product category based on the main intended use selected from the European Product Categorisation System (EuPCS).



- Individual packaging types and their sizes. No ranges are permitted.

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Beyond the safety data sheet (SDS) –adapting existing or including new data

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Review toxicological information

- Toxicological information as required in Section 11 of the Safety Data Sheet in accordance with Annex II to REACH.
- The information is required as free text in the national language* required by the Member state where the mixture will be placed on the market.
- Multimarket submissions must include this information in every language.
- Check quality of the information in Section 11, i.e. no references to other sections of the Safety Data Sheet should be made.

* Or other languages permitted by the Member State e.g. English.

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Assign concentrations to all components

- All components (substances and mixtures) of the mixture must be declared including:
  - the hazardous components
  - non-hazardous components**
- Exact concentrations or concentration ranges allowed
- The allowed range width depends on the concentration and hazard category reported in Annex VIII.
- If the concentration changes or if it goes beyond the allowed limits, then a notification update is required.

**** These components are not normally detailed in the Safety Data Sheet.**

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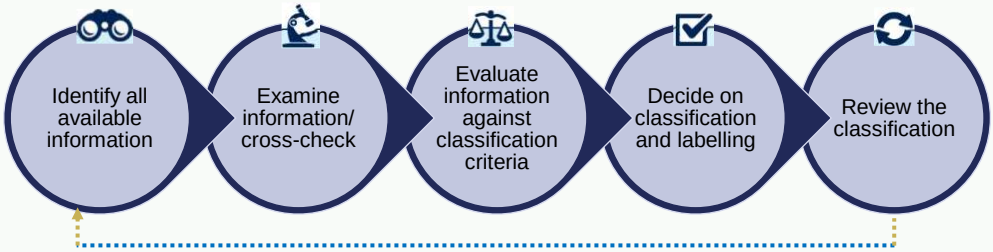
Steps to classify a mixture



Consider what information you actually have available.

Is the information you have relevant and reliable?

Proceed hazard by hazard

Classify and label with appropriate label element

New information is generated all the time – keep up to date!

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Declaring components of 'major concern'

When mixture components are classified for at least one of the hazard categories listed below, their concentrations in a mixture should be expressed as exact percentages, in descending order by mass or volume:

- acute toxicity, Category 1, 2 or 3;
- specific target organ toxicity – single exposure, Category 1 or 2;
- specific target organ toxicity – repeated exposure, Category 1 or 2;
- skin corrosion, Category 1, 1A, 1B or 1C;
- serious eye damage, Category 1.

Hazard classification

As an alternative to providing a concentration as an exact percentage, a concentration range may be submitted in accordance with Table 1 in Part B of Annex VIII (Table 1 below).

Where the exact concentration is higher than 1 %, the upper and lower limits of the concentration bands may be rounded to a maximum of one decimal; where the exact concentration is lower than or equal to 1 %, a maximum of two decimals may be used.

Table 1: Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MiMs)

Concentration range of component contained in the mixture (%)	Maximum width of concentration range to be used in the submission
≥ 25 - < 100	5 % units
≥ 10 - < 25	3 % units
≥ 1 - < 10	1 % units
≥ 0.1 - < 1	0.3 % units
> 0 - < 0,1	0.1 % units

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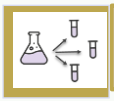
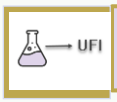
Declaring mixture-in-mixture components

- Check the formulation of any **mixtures in mixtures (MiMs)** and report each component's identity and concentration according to the information available.



Full composition is known from MiM supplier
Report information on all substances at the final mixture level. Aggregate where relevant.



Full composition of the MiM is not known
Report the UFI of the MiM provided it has been already notified in the relevant Member State.

No MiM UFI or MiM not notified in the relevant Member State
List the compositional information from the SDS along with the MiM supplier information.

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Implications on SDS

- The UFI is always to be included in the notification **as well as** on the label/packaging
- No rules on placement -redesign of label to incorporate this new element
- If the product is not packaged or has an industrial use or any other use, the UFI can be included in section 1.1 of the SDS
- Printing of UFIs on the label should be planned to coincide with the submission of information

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Cont...

- In case of mixtures in mixture, if the composition details are not available then it is mandatory to give SDS and supplier information along with poison centre notification
- It is **mandatory** to have UFI on your SDS post from 1 Jan. 2021
- UFI should be from the actual notification done for PCN else it will be treated as dead/inactive UFI
- Mixture classification should be done correctly
- All data should be presented in SDS based on which the classification is done for mixtures
- M-factor or Specific Concentration Limits (SCL) are used that should also be mentioned in section 2 of SDS

Sample Label with UFI

Stepwise Actionable Points

GPC can:

- Do the pre-assessment of your mixtures- to know your PCN obligations
- Compile the data required for PCN notification
- Notification on behalf of your company

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Thank You.

Contact us for global regulatory services

https://gpcgateway.com/

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Masterclass on International Regulation Implicating Chemical and Petrochemical Industry (July 9th)

KKDIK (Turkey REACH): Knowing your registration Obligations

Mr. Mirac Mert Pelister
Turkey Business Coordinator and Regulatory Researcher
Global Product Compliance (GPC) Turkey
Email: mirac@tr.gpcregulatory.com

09/07/2021

Confederation of Indian Industry

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Outline

- KKDIK in a nutshell
- Timeline
- Updates
- Current Situation
- Roles & Responsibilities
- Your Obligations
- Our Role

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KKDIK In a Nutshell

Kimyasalların
Kaydı
Değerlendirilmesi
İzni
Kısıtlanması
Hakkında yönetmelik

Bylaw on
Registration
Evaluation
Authorization &
Restriction of
Chemicals

KKDIK In a Nutshell

- Came into force on June 23rd, 2017
- EU Adaptation policy
- Competent authority: Ministry of Environment and Urbanization
- Merges:
  1. Bylaw on Safety Data Sheets of Hazardous Substances & Mixtures (Until 2024)
  2. Bylaw on Inventory and Control of Chemicals
  3. Bylaw on Restriction and Ban of Hazardous Substances & Mixtures

KKDIK In a Nutshell

The Aim of KKDIK

Article 1

"*The purpose of this Bylaw is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances while enhancing competitiveness and innovation*."

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Timeline

- Submission of registration dossier
  - Chemical safety assessment
  - SDS
  - Test proposals

} if needed

2017

23 Dec 2017

Pre-registration

- Notification of substances
- CLP notification for local manufacturers & importers

31 Dec 2020

1 Jan 2021

Today

Registration

- Notification of substances
- CLP notification for local manufacturers & importers

31 Dec 2023

1 Jan 2024

Post-registration

- Keeping all information up-to-date
- Evaluation communication
- Permit application if needed

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Updates

- Unofficial extension of pre-registration period
  - Extended pre-registrations until the end of 2023
  - Earlier LPR, earlier say in the SIEF!
- LR appointment started on March 2021
  - In relation to this, pre-registrations submitted after 15th of February cannot be deleted!
  - Voting system integrated into KKS
- CHESAR tool will be integrated to KKS
- SME fee calculator integrated into KKS

Updates

- Amendment on CLP (SEA) Regulation
  - Update on the 'List of Harmonized Classification and Labeling'
    - 110 new reference substances, 108 new classifications
    - Mirroring 13th adaptation of EU CLP
  - Change on obligation of Notification
    - If registration under KKDIK is required, CLP notification is also required!
    - New CLP notifications do not count as pre-registration
- Downstream User features will be unlocked by 2022 January 3rd on KKS

Current Situation

- SIEF communications have kick-started as of January
  - LR candidate announcements & appointments going on
- No LPR-related issue so far
- CLP (SEA) Notifications
  - Supply chain notification on KKS
    - KKS users can add downstream users on the portal
    - "Helpdesk of ministry", will be working during registration process
- Individual inventory formation by potential registrants
- Surveys sent by LRs in some SIEFs in progress

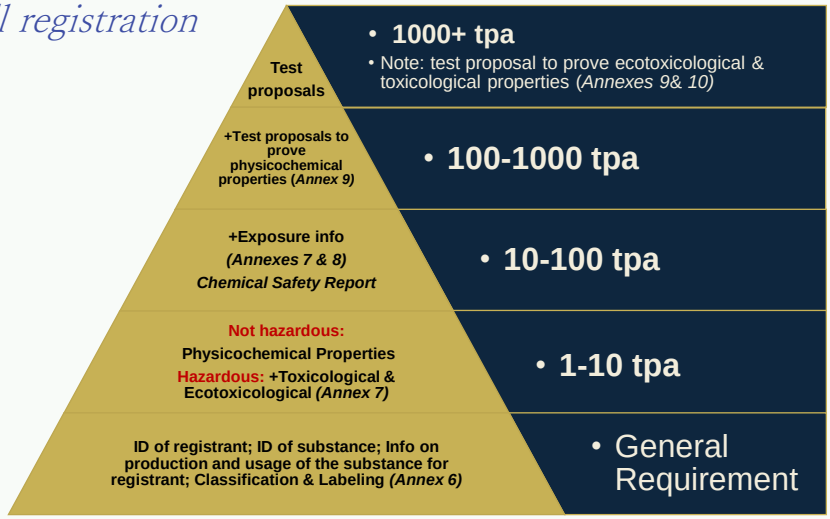
Registration (Exemptions)

- Imported only to be used in biocidals & plant protection
- Human or veterinary medicines
- Substances in *Annexes 4&5*
- Polymers
- Re-isolated intermediates & transported intermediates

- Recycled in Turkey that is registered before
- Exported from a supply chain and reimported by the same supply chain
- Food and feedstock
- Less than 1 ton/year

Registration Data Requirements

Full registration



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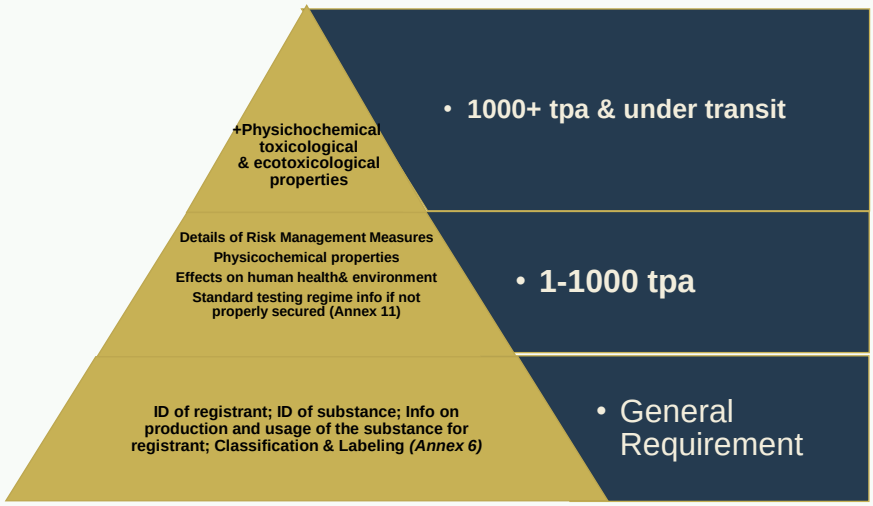
Registration Data Requirements

Isolated intermediate registration



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Registration

Chemical Safety Report (CSR)

- Prepared for 10+ tpa unless is less then:
  - Substance is in mixture => defined threshold in *Annex 1* of CLP
  - PBT/vPvB=> 0.1w% of chemical
- Includes
  - Human health hazards
  - Physicochemical hazards
  - Environmental impact & hazards
  - PBT and vPvB evalutation

➢ Only prepared by a certified Chemical Safety Assessment Expert

Registration

Safety Data Sheet

- Prepared only by a Chemical Safety Assessment Expert* and only in Turkish
- Needed if:
  - Hazardous according to CLP
  - PBT/vPvB
  - Substance is SVHC and in *candidate for authorization* list
- Includes standard 16 headings

*: Not necessarily until 2024

Joint Registration

1) LR is elected
2) SIEF members who would like to join the dossier inform the LR
3) LR creates application, including members and their uses
   - In case an individiual registration is necessary for a SIEF member, application to the Ministry is needed
4) Members complete their part of the dossier individually afterwards

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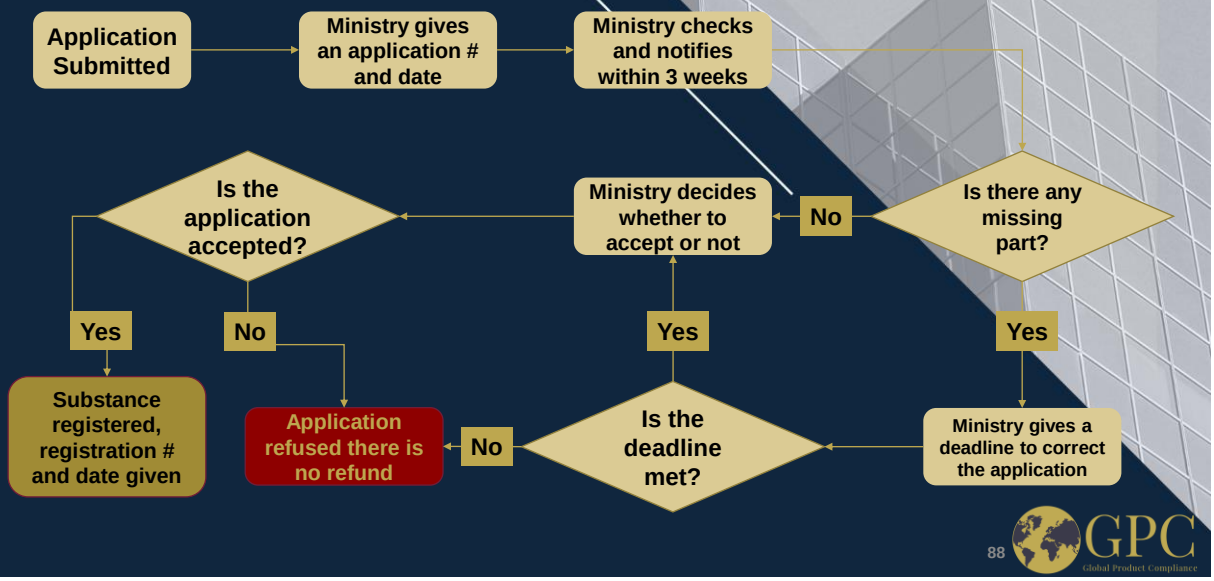
After Submission



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Roles & Responsibilities

- SIEF Participants:
  - Vote among LR candidates or become a candidate
  - Gather necessary data to identify substance, required for sameness survey later on
  - Identify uses for their substance
- Downstream Users:
  - Register on ministry's environment portal if haven't yet and share environmental identity number with suppliers
- Non-Turkish Manufacturers:
  - If pre-registered via OR, share a list of substances
    - Including importer information as above
    - Decide what to register
    - Decide on which role to take
- OR
  - Start and participate in SIEF communications
  - Define the most cost-effective strategy to protect client interest
  - Reflect client intention and represent in SIEFs

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Your Obligations

- Keep information regarding substances up-to-date with your OR
- Share importer list for your substances
- CLP notification (optional)
- Respond to surveys sent by GPC as soon as possible for best represention, let us know if you haven't received any survey
- Share information provided by GPC with your buyers

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Our Role

- GPC is experienced with LR and consortia management for 400+ substances
- Currently taking lead ~250 SIEFs already in Turkey
- We will:
  - Represent your best interests in the SIEF
  - Take LR position whenever possible
  - Manage communication down the supply chain
  - Follow most economic strategies for your compliance
- Our supply chain portal will soon be available for Turkey-REACH compliance management as well

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GPC Global Product Compliance

Your seamless extension in global regulatory compliance

As GPC Turkey we have
3200+ pre-registered substances
~300 happy clients
We are active in 1600+ SIEFs

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Thank You.

Contact us for global regulatory services


https://gpcgateway.com/


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